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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/882,509	06/15/2001	Mosuvan Kuppusamy	51321-003	8339

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DEWITT ROSS & STEVENS S.C.
8000 EXCELSIOR DR
SUITE 401
MADISON, WI 53717-1914

EXAMINER

MONSHIPOURI, MARYAM

ART UNIT PAPER NUMBER

1652

DATE MAILED: 12/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/882,509

Applicant(s)

KUPPUSAMY ET AL.

Examiner

Maryam Monshipouri

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 6 and 12-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7-11 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

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Claims 1-5 and 7-11 are still at issue and are present for examination. Claims 6 and 12-21 are withdrawn as drawn to non-elected invention.

Applicants' arguments filed on 9/24/04 , have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

In traversal of the rejoinder of claims 12-21 with claim 6 of Group II in the previous office action, applicant argues that the office has failed to provide any reasons or examples to support the new restriction, as required by MPEP section 803, and hence, in view of applicant said rejoinder is improper. Further, applicant objects to the fact that rejoinder had been made final before applicant had a chance to respond thereto.

Firstly the point is well taken that applicant is entitled to respond to the examiner's new rejoinder issue and for said reason the examiner is addressing applicant's traversal arguments as follows: in claims 12-21 the claimed subject matter is a DNA construct comprising a promoter operationally linked to a secretion signal that is operationally linked to a DNA encoding streptokinase. Clearly the DNA construct of Group II is totally different, structurally and functionally, to that of Group I invention and the streptokinase produced by said DNA construct results in soluble streptokinase and not enzyme in inclusion bodies. Therefore, for said reasons the rejoinder of claim 6 with claims 12-21 remains and is hereby made **final**.

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With respect to applicant's additional arguments in traversal of the original restriction letter the examiner would like to point out that the reasons for holding a restriction were already discussed twice, in the original restriction letter and the last office action, respectively. Hence the examiner will no longer address applicant's new arguments.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-2, 4-5 and 7-11 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention as indicated in the previous office action. In traversal of this rejection applicant argues that the Office has taken the position that "streptokinase is not a sufficiently precise word to convey to one of skill in the art that the present applicants were in possession of the invention as broadly claimed. However, as evidenced by exhibit A, enzymes have and continue to be named, described in catalogs, listed and indexed by their functional names ending in "-ase". Further according to applicant, exhibits B and C support the fact that "streptokinase" fall within EC 3.4.21.7, namely hydrolases that act on peptide bonds,

that are serine endopeptidase and that act upon a plasmin substrate, rendering the phrase "streptokinase" very precise.

Applicant then refers to few U.S. and German patents wherein streptokinases are produced transgenically (which is assumed to mean recombinantly) or otherwise. He also refers to some streptokinases and their precursors, which display 87-98% homology to one another.

Therefore in view of said arguments applicant believes that the phrase "streptokinase" is well known and well defined in the art and this rejection should be withdrawn.

These arguments were fully considered but were found to be **unpersuasive** for the following reasons: firstly the examiner did not draft the 112 first rejection due to lack of function of the phrase "streptokinase" but its lack of structure. The examiner is fully aware that what said phrase refers to in terms of activity, as evidenced by ample knowledge of the prior art. However, with respect to the issue of streptokinase structure applicant is reminded that he/she, as stated previously, is claiming streptokinases from all sources and species such as mammals, mollusks, amphibians etc., including some streptokinases that have not been isolated yet, and thus said phrase embraces an enormous scope, which in contrast to applicant's opinion, renders it totally imprecise. This is because, providing few species (assuming that streptokinase precursors can be considered to be a species of the claimed genus) that applicant recited in his response to last office action is insufficient to adequately define the broad genus of streptokinases and for said reason, in addition to those provided previously, the rejection is maintained.

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Since DNA encoding streptokinase is under rejection all products comprising them (claims 1-3) and methods of using them (claims 4-5, 7-11) also remain rejected.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5, 8-9 and 11 remain rejected under 35 U.S.C. 102(b) as being anticipated by Pupo et al. (cited previously) according to previous office action. In traversal of this rejection applicant argues that Pupo's main purpose as indicated in page 1120 left column, is to prepare soluble streptokinase (SKC) and not streptokinase in inclusion bodies. Further, pACS-2 plasmid does not drive the expression of streptokinase as inclusion bodies because, even though figure 3, lane 6 of Pupo displays the existence of an insoluble streptokinase fraction in E. coli. Lysate said insoluble fraction is cited by Pupo to be contaminated by soluble streptokinase and was mostly washed off with buffers.

These arguments were fully considered but were found **unpersuasive**. Firstly, the examiner would like to point out that what Pupo's intention was in expressing its streptokinase (SKC) is, in fact, irrelevant to the anticipatory role of its disclosure against this invention. As applicant is well aware said reference was cited for displaying some insoluble SKC prepared in E. coli and not for what the authors intended to prepare.

Secondly, the examiner agrees that Pupo in page 1122 indicates that most of insoluble SKC fraction could be washed off with buffers but said reference fails to say that all of said insoluble fraction was washed off in its entirety. Therefore, Pupo, whether he wanted or otherwise, did prepare some (small amount) insoluble SKC (in inclusion bodies) and for said reason said reference remains anticipatory to this invention.

No claims are allowed.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maryam Monshipouri whose telephone number is (571) 272-0932. The examiner can normally be reached on 7:00 a.m to 4:30 p.m. except for alternate Mondays.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnanthapu Achutamurthy can be reached on (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Maryam Monshipouri Ph.D.
Primary Examiner
